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EXAMINER	
DUFFY, PATRICIA ANN	
ART UNIT	**PAPER NUMBER**
1645	

DATE MAILED: 06/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/076,634	HABERMANN ET AL.	
	Examiner	Art Unit	
	Patricia A. Duffy	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) *7 and 8* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6 and 9-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-23* are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *9-13-02*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The response to the restriction requirement filed 1-5-2004 has been entered into the record. Claims 1-23 are pending.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

The claimed prior-filed provisional application 60/270,593 was filed in a language other than English and an English-language translation of the prior-filed provisional application and a statement that the translation is accurate were not previously filed in the prior-filed provisional application. Applicants are required to comply with the translation and certification of the provisional application translation within the time period set forth in this office action. Failure to comply within this time period will result in abandonment of this application. Applicants are directed to CFR § 1.78(a)(4)(iv).

Specification

The disclosure is objected to because of the following informalities:

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The use of the trademarks at least at pages 3, 4, 15 and 23 have been noted in this application. They should be capitalized wherever they appear and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Applicants should review this application in its entirety and correct the numerous citations of trademarks present therein.

Information Disclosure Statement

The information disclosure statement filed 9-13-02 has been considered to the extent possible. Certain foreign language publications have been lined through because they are not in compliance with 37 CFR 1.98(a)(3)(i) which requires a concise explanation of the relevance, as it is presently understood by the individual designated in §1.56(c) most knowledgeable about the content of the information, of each patent, publication, or other information listed that is not in the English Language. The concise explanation may be either separate form applicants' specification or incorporated therein. A initialed copy is enclosed.

Election/Restrictions

Applicant's election with traverse of Group I in the response of 1-5-04 is acknowledged. The traversal is on the ground(s) that there is no serious search and examination burden and that distinct inventions is insufficient basis by itself to support a restriction requirement. This is not found persuasive because The term "distinct" is defined to mean that two or more subjects as disclosed are related, for example, as product and method of use, etc., but are capable of separate manufacture, use or sale as claimed, and are patentable over each other (see MPEP 802.01). In the instant situation, the inventions of Groups I and II are drawn to distinct inventions which are related as separate products capable of separate manufacture, use or sale as described in the previous Office Action. Restrictions between the inventions is deemed to be proper for the reasons previously set forth. In regard to burden of search and examination, MPEP 803 states that a burden can be shown if the examiner shows either separate classification, different field of search or separate status in the art. In the instant case

a burden has been established in showing that the inventions of Groups I and II are classified separately necessitating different searches of issued U.S. Patents.

The requirement is still deemed proper and is therefore made FINAL.

Claims 7 and 8 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the response of 1-5-04.

Double Patenting

Claim 1-6 and 9-23 of this application conflict with claims 1-3 and 7-20 of Application No. 10/076,631 and claims 1-3 and 7-20 of Application No. 10/076,632. 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-6 and 9-23 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 and 7-20 of copending Application No. 10/076,631. Although the conflicting claims are not identical, they are not patentably distinct from each other because the specifically claimed and disclosed species anticipate the instantly claimed invention.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-6 and 9-23 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 and 7-20 of copending Application No. 10/076,632. Although the conflicting claims are not identical, they are not patentably distinct from each other because the specifically claimed and disclosed species anticipate the instantly claimed invention.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6 and 9-23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.
Claims 1-6 and 9-23 are drawn to a genus of nucleic acids encoding a fusion protein and methods of use thereof for fermentation production and isolation of the fusion proteins. The specification teaches at Examples 1-3 construction of nucleic acids encoding fusion proteins comprising (lepirudin or ser-huridin or ala-hirudin)-cleavable linker-simian proinsulin and the fermentative production and purification thereof from a *E. coli* host cell transformed with a plasmid encoding the fusion protein (see page 22 [078]), wherein the plasmid further comprises a promoter and a signal secretion sequence. The claims are drawn to a genus of nucleic acids encoding fusion proteins, plasmids, host cells, and methods of production and purification thereof. Written description for a claimed genus can be satisfied through description of a representative number of species by actual reduction to proactive, reduction to drawings, disclosure of relevant identifying

characteristics (structure, functional characteristics coupled with a known or disclosed correlation between structure and function, physical and or chemical properties, sufficient to demonstrate that applicants were in possession of the claimed genus. Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.) Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmacentical Co. Ltd., 18 USPQ2d 1016. Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that: " An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention." *Fiers v. Revel* , 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id. at 1170, 25 USPQ2d at 1606. Further, the species described in the specification must be representative of the entire genus (MPEP § 2163). In the instant case the genus of nucleic acids comprising fusion proteins is highly variant. Substantial variation between the members of the genus is permitted and therefore the specification must describe a sufficient variety of species to reflect written description of the claimed genus. While the specification describes several alternative members for "S" a nucleic acid coding for a signal sequence that increases yield, it fails to describe alternatives for the structures of

"Asm", "Rn", "Y", "P" and "T" which encompass species of widely variant structure and function. Further, the specification discloses "F" as an amino acid sequence which allows secretion of a protein encoded by Y into a fermentation medium. The protein "F" is then limited to specific hiruidin derivatives. However, the specification fails to describe hiruidin as "allowing secretion of a protein encoded by Y into a fermentation medium. In fact, hiruidin in the absence of a secretory leader/peptide sequence does not get secreted into the fermentation medium. Applicants have not demonstrated that hiruidin or any derivative or variant therereof "allows the secretion of a protein encoded by Y into a fermentation medium" as is specifically claimed. There is no data indicating that hiruidin alone, in the absence of a signal sequence for secretion, is in fact secreted into the fermentation medium. Therefore, the specification utterly fails to teach a single protein "F" that "allows secretion of a protein encoded by Y into a fermentation medium" as is recited in the claim. As such, the disclosure of three specific sequences fails to provide adequate written description of the claimed genus of nucleic acid sequences and fails to provide description of any nucleic acid sequence with the claimed property of "F". Given the lack of written description of a representative number of nucleic acid sequences for each of the individually claimed highly variant structures with different functions, the lack of any protein sequence meeting the limitation of "F", the limited examples of specific fusion proteins of the specification do not describe the claimed invention in such full, clear, concise and exact terms to indicate to a skilled artisan that Applicant was in possession of the claimed invention.

Claim 1-6 and 9-23 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the particularly disclosed nucleic acids encoding fusion proteins, plasmids, bacterial host cells and methods of fermentative production in a bacterial cell and isolation of the fusion proteins thereof from a culture supernatant as particularly set forth in the Examples of 1-9 of the specification, it does not reasonably

provide enablement for the claimed nucleic acids encoding fusion proteins, plasmids, host cells, methods of making and purification. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

As to claim 1 and every claim dependent thereon, the claims are drawn to a genus of nucleic acids encoding fusion proteins having the property of F-Asm-Rn-Y wherein F is a nucleic acid sequence coding for an amino acid sequence which allows secretion of a protein encoded by Y into a fermentation medium, As is a chemical bond or a nucleic acid sequence comprsising a codon, m is an integer from 0-10, R is a chemical bond or an arginine codon, n is 0 or 1 and Y is a nucleic acid coding for a protein of interest. The sole description of the specification of "F" is claim 4, which indicates that F encodes lepiruidin, ser-hirudin or ala-hiruidin. The function of the nucleic acid denoted "F" as recited in claim 1 (and every claim dependent thereon) is to allow secretion of a protein encoded by Y into a fermentation medium. The disclosed proteins do not provide this function. There is no teaching in the art or in this specification that teaches that the disclosed lepiruidin, ser-hirudin or ala-hiruidin have endogenous sequences that provide for and "allow" secretion of a protein fused to it (i.e. the instant "Y"). In each example of the specification, the nucleic acid encoding the hiruidin-proinsulin fusion protein is fused 5' with a well known signal sequence providing for secretion of the protein into the fermentative medium. Signal sequences are defined in the art as a peptide present on proteins that are destined either to be secreted or to be membrane components (see On-Line Medical Dictionary). The specification is devoid of data indicating that any of lepiruidin, ser-hirudin or ala-hiruidin have endogenous sequences that provide for and "allow" secretion of a protein fused to it and the art teaches that secretion of hirudin is provided by fusion to a secretion signal (see WO 91/09125, page 22, first full paragraph). Therefore, the art does not recognize that hiruidin or any variant thereof has the ability to function to allow secretion of itself or any other protein fused to it into a fermentation medium. As such,

the specification fails to describe and enable any fusion protein wherein "F" is limited as claimed. As to claim 2, and every claim dependent thereon, the specification fails to disclose or describe a single nucleic acid sequence that is "T", an untranslated expression-enhancing nucleic acid sequence as such, the specification provides no guidance for suitable nucleic acids of the art. The description is by mere function alone and does not describe a single sequence that meets this functional limitation as such one skilled in the art could not make and use such to construct the claimed nucleic acid sequences. The selection and combination of appropriate sequences for secretion into a fermentative medium is problematic. First, the specification discloses only plasmids suitable for fermentative expression and secretion of the specific species in *E. coli* and lacks guidance on specific plasmids for other bacteria, including the claimed *Bacillus subtilus*. The art is replete with problems associated with expression and secretion using different systems. For example, EP 0511393 teaches that methods using *Bacillus subtilis* are problematical because plasmids are generally unstable, resulting in the curing of plasmids, making protein production difficult and the protein products in the medium are likely to be digested by its own proteases that are also secreted (page 2, lines 44-48). The specification provides no guidance on particular plasmids that are suitable for production of any of the proteins of any of the Examples of the specification. No guidance is given for any particular stabilizing structural modifications and it is not readily apparent that the disclosed plasmids for production of the fusion protein in *E. coli* a gram negative bacterium, will work unaltered in *Bacillus subtilis* a gram positive bacterium, or the claimed *Streptomyces lividians*. Further, even using *E. coli* as a host microorganism, the PhoA leader sequence describe in the specification directs protein production toward the periplasm of *E. coli* and does not facilitate secretion into a fermentation medium (see EP 0511393, page 55-60). Further, the specification fails to teach any chromosomal integrative vector and production of proteins therefrom. As such, the claimed nucleic acids encoding fusion proteins, plasmids, host cells and anything that depends therefrom is not enabled by this

specification as filed. As to the generic methods of production, isolation and purification of fusion proteins (claims 14-23), these claims are not enabled. The purification of individual proteins/fusion proteins is highly empirical in nature. The skilled artisan requires key characteristics pf the protein and/or critical purification steps before even preliminary purification approaches can be devised. The steps of protein purification are different for each protein and vary a great deal from protein to protein. There are hundreds of individual purification procedures and exponential combinations thereof. There is no one single purification method for different proteins. As such, the purification method disclosed for the disclosed fusion protein, would not arguably work for any other fusion protein. The specification does not teach that this purification method allows the isolation of any of a variety of different fusion proteins. General methods described do not provide specific guidance needed for particular proteins. The art teaches that "One should not read published descriptions of successful purification and cloning attempts, or review of methods useful in the attempts, and presume that cloning and protein purification is a routine approach with the person of ordinary skill practices like falling off a long one given a published description of an assay for a protein. A description of an assay for a protein does not teach or suggest any particular characteristic of the protein which would assist the skilled artisan in its purification, such as pI, size, shape, etc. General methods described in a review contain no hint of suggestion about the necessary approach for the actual purification of a specific protein. The requirements of purification vary so much from protein to protein, that the knowledge gained from purifying one protein can be useless in devising a protocol to purify another, and in fact a detergent or other element used successfully in one protocol can inactive or destroy another protein." (BIO Critical Synergy: The Biotechnology Industry and Intellectual Property Protection, Biotechnology Industry Organization, Presentations October 17, 1994, page 75-107, page 105, second full paragraph in particular). As such, one of skill in the art would have substantial reason to doubt that the protocol devised for

purification of the disclosed species from an *E. coli* fermentative supernatant is not broadly applicable to any fusion protein as is claimed.

In view of the foregoing reasons, the lack of written description of the specification, the lack of direction and guidance by Applicants, and in the absence of supplemental information, the specification does not teach how to make and use the nucleic acids, does not teach how to broadly apply the production and purification methods without undue experimentation and the claims should be limited to the disclosed combinations and methods as set forth in Examples 1-9.

Claims 1-6 and 9-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As to claim 1 and every claim dependent thereon, the claim recites Asm where As is a chemical bond or a nucleic acid sequence comprising a codon. If "m" represents a chemical bond, it is unclear how individual chemical bonds are linked. Clarification is requested.

As to claim 3, the following phrases have no meaningful interpretation "smompa derived from", "ecoompc derived from", "af009352 derived from", "aeoynxa derived from" or "stomps1 derived from" because these acronyms apparently represent specifically claimed nucleic acid sequences not described nor specifically defined in the specification. These acronyms have no art accepted definitions, nor art defined structure. The specification provides no definition of such. As such, the skilled artisan would not be readily apprised as to the metes and bounds of the claimed encoding nucleic acids.

As to claim 4, the recitation of "Ser-hirudin" or "Ala-hirudin" have no meaningful interpretation in view of the specification because the specification does not describe nor define what these apparent variants are or are intended to encompass. Therefore, the

skilled artisan would not be readily apprised as to the metes and bounds of the claimed encoding nucleic acids.

As to claim 6, the claim recites that the nucleic acid encodes for the protein of interest, this appears to broaden the claim. Additionally, the recitation is confusion because it is unclear as to how it structuraly further limits the claimed nucleic acid encoding a fusion protein. Clarification is respectfully requested.

As to claim 14 and every claim dependent thereon, the claims recite a process from fermentative production of a fusion protein, but fail to recite a host cell and conditions under which a fermentative process can occur and as such these claims are incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01.

As to claims 15, 16 and 17 the claims recite separating a host cell, fusion protein or precipitating from a supernatant, however no supernatant is formed and therefore it is unclear how a supernatant is generated.

As to claim 17, the claim recites precipitation components of a culture medium, however, no culturing step in culturing medium is provided for in the previous claims.

As to claims 18 and 22, the process of fermentation is a chemical process involving an enzymatically controlled anaerobic breakdown of an energy-rich compound. However, none of the required constituents for a fermentative process are recited in the claim and the process of fermentation does not provide a fermentation "supernatant" or a "fermentation medium". Supernatant is a clear liquid overlaying material deposited by settling, precipitation or centrifugation. As such, there is no supernatant isolated. The fermentative process provides for both. There is no step that provides for supernatant isolation. As such, the process as defined is clearly inconsistent with the defined meanings of the art.

As to claims 19, 20 and 23, the term "the host cell" lacks antecedent basis in the independent claim 14.

As to claim 21, the claim is uninterpretable, the claim recites obtaining the fusion protein by the process of claim 14 and releasing insulin therefrom, however, the fusion protein of claim 14 is not directed to an insulin fusion protein.

Where applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999). The term " signal sequence" in claims 2-5, is used by the claim to mean "a nucleic acid sequence that increases yield", while the accepted meaning is "a peptide present on proteins that are destined with to be secreted or the be membrane components. It is usually at the N terminus and normally absent from the mature protein. Normally refers to the sequence (ca 20 amino acids) that interact with signal recognition particle and directs the ribosome to the endoplasmic reticulum where co translational insertion takes place. " The term is indefinite because the specification does not clearly redefine the term and the term does not provide for the property of increasing yield.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 6, 9-15, 17, 22 and 23 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Dawson et al, WO 91/09125 published 27 June 1991.

Dawson et al teach a nucleic acid encoding a promoter-signal peptide-hiruidin-cleavable linker-hirudin-enhancer or nucleic acid encoding a promoter-signal peptide-hiruidin-cleavable linker-streptokinase-enhancer in plasmids contained in host cells (see Examples 1-15) and methods of production therefrom, isolation of the fusion from supernatants and cleavage of linker and release of active streptokinase and hirudin in E. coli and S. cerevisiae. As such, the claims are anticipated by the prior art.

Status of the Claims

Claims 1-6 and 9-23 stand rejected. Claims 7 and 8 are withdrawn from consideration as drawn to non-elected inventions.

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy whose telephone number is 571-272-0855. The examiner can normally be reached on M-F 6:30 pm - 3:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864.

The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Patricia A. Duffy, Ph.D.

Primary Examiner

Art Unit 1645